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REMARKS

JUN 21 2007

**Claims 1- 19 are rejected under 35 U.S.C. 103 as being unpatentable over
Knox et al. (U.S. Patent No. 5, 814, 003) further in view of Sabin et al (U.S. Patent
No. 5,984,953) .**

Knox et al (U.S. Patent No. 5,814,003 hereinafter "Knox") discloses a device for positioning a pulsatile bladder about a portion of a user's body. The device consists of an inner sleeve and an outer sleeve extending over the inner sleeve. Knox does not disclose a moldable gel pad. Knox also does not disclose or teach the positioning of the moldable gel pad within the sleeve.

Sabin et al (U.S. Patent No. 5,984,953 hereinafter "Sabin") discloses a self-heating, disposable heating pack utilizing an exothermic chemical reaction. The temperature of the heat pack is altered with the use of an exothermic chemical reaction and evaporation of a solvent. There is no disclosure of pressure or compression in Sabin. The heat pack changes in stiffness and can not be inserted in a stocking and is not moldable. Sabin's heat pack which is stiff cannot mold to fit the recesses which are located about an ankle. The moldable gel pad of the claimed invention cannot be replaced by a stiff heat pack.

Claims 1-19 recite subject matter that is not disclosed in either reference.

Claims 1-19 Missing Element: A moldable gel pad

Further, neither Knox nor Sabin disclose a moldable gel pad. Claim 1 recites a

moldable gel pad in a sleeve of a stocking. Knox has a pulsatile bladder with fluid such as air being pumped into it. The pulsatile bladder is not a moldable gel pad. The Examiner is attempting to equate a pulsatile bladder with a moldable gel pad and they are not the same.

The pulsatile/bladder will not fill in a crevice or recess adjacent to a bony prominence like those that exist in proximity to an ankle. The heat pack of Sabin releases heat and is not a moldable gel pad. It is not designed to be malleable and to fit close to the skin which transfers the pressure of the outer portion of the stocking to the patient's skin to reduce venous insufficiency as in the claimed invention. (See paragraph 15 of the Shook et al 20040158283 A1 Publication). Both references lack a moldable gel pad structure. As a result, claims 1-19 are allowable.

Missing Elements: Compression stocking comprising a sleeve and a moldable gel pad within sleeve

Further, claims 3, 4, 6, 8, 11, 12, 17, and 19 recite a compression stocking comprising a sleeve and a moldable gel pad which is not disclosed in either reference. Knox discloses an inner wall of a sleeve which is a compression stocking. Knox does not disclose a moldable gel pad which is held in place by an outer wall of a sleeve to enable the user to pull a compression stocking thereover.

Knox specifically teaches away from this claimed structure of the instant invention by stating that in Col 2, lines 48-55: "The stocking desirably includes an inner tubular

sleeve and an outer tubular sleeve which is relatively less elastic than the inner sleeve...

Further, because the outer layer 14 is less elastic than the inner layer 12, the tendency for the bladder 22 to be pressed uncomfortably against a wearer's limb by the stocking 10 is reduced." As a result, Knox teaches away from the claimed invention where the moldable gel pad is held in position by the outer portion of the sleeve to enable the user to pull a compression stocking thereover. Sabin also lacks a compression stocking and a moldable gel pad.

As a result claims 3, 4, 6, 8, 11, 12, 17, 19, and 20 are not made obvious by Knox in view of Sabin and are believed to be allowable.

Missing Elements: Positioning a gel pad ... to apply pressure, Claims 16 -19

Claims 16 -19 are method claims for reducing venous insufficiency. Claim 16, as amended, includes the step of "positioning a moldable gel pad about said foot, ankle and leg of said patient to apply pressure to reduce venous insufficiency. " Neither, Knox, Sabin, nor Knox in view of Sabin include the elements of a moldable gel pad for applying pressure. Further, the heat of Sabin is not equivalent to pressure or even properly combinable with Knox to arrive at the invention as recited claims 16-19.

Knox and Sabin Teach Away from Claimed Structure in Claims 1-19

Both references teach away from the claimed structure of the instant invention. Knox teaches two concentric sleeves with space therebetween for holding a pulsatile bladder and tubing. First, the sleeve of Knox is different in that the outer layer in Knox is

less elastic than the inner layer reducing the tendency for the bladder to be pressed uncomfortably against a wearer's limb (See Column 4, lines 52-54). The pulsatile bladder requires space to operate. This teaches away from the instant invention where the moldable gel pad is held close to the skin and is designed to be malleable so that it fits into recesses adjacent to bony prominences. Knox and Sabin teach pulsation or heating and they are not malleable. Both references teach away from the instant invention.

Lack of Teaching, Suggestion, or Motivation in Knox and Sabin

Further, there is no teaching, suggestion, or motivation that would allow one of ordinary skill in the art to combine the heat pack of Sabin with the loose fitting outer and inner concentric sleeves of Knox. The heat pack of Sabin is not equivalent to the moldable gel pad of the instant invention. First, the heat pack of Sabin is not a moldable gel pad. The heat pack consists of several different materials designed to react and change in temperature resulting in a change in stiffness. The heat pack is not uniform, homogeneous, or designed to be fitted close to the surface of the skin. The heat pack in Sabin would not be able to be held close to the skin in a recess near a bony prominence because the outer sleeve of Knox is loose fitting. Secondly, the heat pack of Sabin is not properly combinable with Knox to result in the structure as claimed. Heat packs can not be compressed against the skin without causing damage or burns to the skin. In addition, the heat pack of Sabin is stiff and does not fit to the contour of a recess in proximity to an ankle. As a result, a person of ordinary skill in the art would not look to combine Knox

and Sabin.

Neither reference provides any teaching, suggestion, or motivation for the combination of moldable gel packs within the sleeve of a stocking. MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. 'The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.' Here, it is respectfully suggested that the Examiner is improperly combining the references as Sabin, Knox, and the claimed invention are directed to different problems. Knox discloses that the pulsatile bladder stimulates blood flow by virtue of its pulsations along the calf of a wearer. Knox is not useable about an ankle of a wearer where ulcerations form due to venous insufficiency. Sabin is a pack for heating and is not malleable and would not work with Knox.

Failure to Identify a Specific Understanding or Principle

It is respectfully suggested that the Examiner has failed to identify a specific understanding or principle that would have motivated one of ordinary skill in the art to make the combination to result in the claimed structure of the instant invention. In *In re*

Kotzab, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000) the court held that a "finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the claimed invention] to make the combination in the manner claimed" must be made. In the instant application, the Examiner has not identified a specific understanding or principle within the knowledge of the skilled artisan that would have motivated one with no knowledge of the claimed invention to make the combination in the manner claimed. Nowhere does the Examiner identify the artisan given the differences in the problems to be solved, nor does the Examiner explain the motivation for combining the structure of the references. Neither reference is directed to solving the problem of the instant invention.

As a result claims 1-19 are not made obvious by *Knox* in view of *Sabin*.

Claims 3 and 4 were rejected under 35 U.S.C. 103(a) as being unpatentable over by Ricci et al (U.S. Patent Application Publication No. US2002/0172781) and further in view of Sabin et al (U.S. Patent No. 5,984,953).

Ricci et al (U.S. Patent Application Publication No. US2002/0172781 hereinafter "Ricci") is a composite elastic stocking comprised of two parts.

Missing Structure : Moldable gel pad

As discussed above, the disposable heat pack in *Sabin* is not a moldable gel pad and *Ricci* does not have a moldable gel pad. *Ricci* is simply a stocking and does not have a pocket or sleeve but instead is foldable to allow medication to be placed underneath the

stocking. Sabin's heat pack is not the equivalent of the moldable gel pad in the instant invention. Sabin's heat pack contains liquids which react to release heat at varying degrees of stiffness. Sabin's heat pack is not a moldable gel pad, it contains liquid and has stiff sections. Sabin does not teach use of the heat pack in a compression environment.

Missing Structure : Sleeve and an opening in said sleeve

Neither Ricci, Sabin, nor Ricci in view of Sabin include a sleeve for holding a moldable gel pad. Ricci's ability to fold stocking parts does not constitute a sleeve. The moldable gel pad is placed in a sleeve so that the moldable gel pad is not directly contacting the skin (See Shook Col. 4, Paragraph 55, "The moldable gel pad resides in contact with the inner and outer portions of the understocking but does not contact the skin or bandages of the patient.") Ricci does not teach placing medication or a moldable gel pad in a sleeve. The stocking of Ricci does not include a sleeve. Page 1, paragraph 23 Ricci teaches the use of the two part stocking to facilitate more easily changing medication and dressings of the skin. There is no sleeve disclosed in Ricci for holding medication that could be used in combination with Sabin to arrive at the structure as claimed.

Further, the stocking of Ricci is not properly combinable with the heat pack of Sabin for the reasons stated above namely that a heat pack which provides heat through an exothermic reaction is not moldable against recesses in human appendages. Holding the heat pack of Sabin in proximity to the skin, may also result in serious burns to the

skin. Sabin indicates that one of its uses is to heat food, so the likelihood of burned skin is high if the pack is placed in proximity to the skin. As a result, Ricci is not properly combinable with Sabin to result in structure of the claimed invention.

As a result, claims 3 and 4 are not made obvious by Ricci in view of Sabin, and claims 3 and 4 are believed to be allowable.

Claims 1, 2, 9-19 are rejected under 35 USC 103 (a) as being unpatentable over Gold (U.S. Patent No. 5,187,814) and further in view of Sabin et al (U.S. Patent No. 5,984,953).

Gold has been studied. Gold does not disclose a moldable gel pad. The word "gel" is not used in Gold. A heater pack is not a moldable gel pad and it does not appear from Gold that the reference is using the terms heater pack to mean a moldable gel pad. Gold does not teach a compression stocking. In fact, the words "compress", "compression", and "stocking" are not even used in the Gold disclosure. Compression stockings are known in the art as set forth in applicant's specification referring to US Patent No. 5,823,195. The sock depicted in Figs. 6 and 7 of Gold is not a compression stocking. As discussed above Sabin also lacks a moldable gel pad. Both Gold and Sabin disclose structure for the release of heat. Heat is not the same as compression. Further, there is no teaching, suggestion, or motivation in Gold in view of Sabin that would allow one of ordinary skill in the art to arrive at the invention as claimed.

MPEP section 2143.01 quoted above indicates that the prior art must suggest the

desirability of the claimed invention. Here, it is respectfully suggested that there is no basis for combining Gold and Sabin to result in the structure as claimed. Neither Gold nor Sabin teach any of the process steps recited in claims 16-19. Specifically, Gold and Sabin do not teach positioning a moldable gel pad within a sleeve of an understocking worn by a patient. Nor do the references hint about the stocking being a compression stocking or the overstocking being a compression stocking. Sabin's heat pack which is stiff cannot mold to fit the recesses which are located about an ankle. The moldable gel pad of the claimed invention cannot be replaced by a stiff heat pack. Both references lack structure, teaching, suggestion, and motivation to make the claims obvious. As a result, claims 1, 2, and 9-19 are not made obvious by Gold in view of Sabin. Reconsideration of claims 1, 2, and 9-19 is requested.

Claim 7 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Gold (U.S. Patent No. 5,187,814), modified by Sabin, et al. (U.S. Patent No. 5,984,953), and further in view of Lyles (U.S. Patent No. 6,001,122).

As demonstrated above, Gold clearly lacks the elements of the instant invention and contains teaching contrary to the instant invention. Gold is not properly combinable with Sabin to arrive at the invention recited in claim 7. The disposable heat pack of Sabin is not the equivalent of a moldable gel pad. Lyles appears to be a wrap around device with a hot or cold pack wrapped around a stocking. The word "stocking" is not used in Lyles. The device in Lyles is not a stocking and it does not extend 360 degrees around the foot

of a user. The term "360" does not appear in Lyles. Rather, each closed edge is in the form of a pleat 23.

Gold and Lyles disclose pockets. The pockets are limited to only one portion of the device. The claimed sleeve as recited in claim 7 is concentric with the stocking and is formed continuously about the stocking, for example, it extends 360° within the stocking. (See for example Figs. 1 and 7 of Shook et al.) Gold, Lyles, and Sabin whether used alone or in combination lack a sleeve which extends 360 degrees within a stocking. Claim 7 is not made obvious by Gold, modified by Sabin, and further in view of Lyles and as a result claim 7 is believed to be allowable.

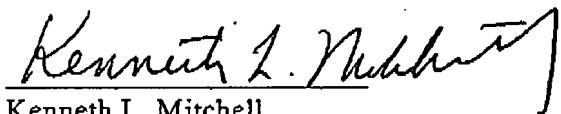
Summary

Applicant claims structure that is different and not made obvious by references cited by the Examiner. Claims 1-19 and 21-24 are allowable. Consideration of claims 1-19 and 21-24 is requested.

The undersigned invites a call from the Examiner to expedite the processing and allowance of this patent application.

Respectfully submitted,

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